EXHIBIT 47

MICHAEL R. REED

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In re Bair Hugger Forced
Air Warming Products
Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

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VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

- -

London, United Kingdom

Taken December 4th, 2016 By Rose Kay

Job No. 115951

communications about published studies.
MR. GORDON: The communications about published studies relate to criticisms of the published studies and the way to respond to and address those criticisms and why things were or were not done on a particular --
THE EXAMINER: Let's look at the e-mails.
MR. GORDON: That is what we are --
THE EXAMINER: Let's get to the e-mails. I am not persuaded at the moment. If you show me relevant e-mails, I may be persuaded.
MR. GORDON: I will get to it, but you know --
THE EXAMINER: No, I am not going to allow this type of questioning to continue, unless you lay a basis with proper e-mail references to this witness. I am simply not going to allow it to continue.
MR. GORDON: That is fine. I appreciate that Mr. Reed is kind of cutting to the chase and getting things out, that I will get to eventually. So I will stick to the documents. I apologize. This is going to take a little bit longer this way.
BY MR. GORDON:
Q. Let's go to the McGovern paper, and I want to focus on the second part of the study, the comparison or the -- what you described as the clinical component.

A. Yes. I would like to speak to you about that.
THE EXAMINER: Well, let's get to it first, where it is; so that those of us who are not familiar with this document can identify it.
A. So 540.
THE EXAMINER: Yes, I have got that. Where in the document are you talking about?
MR. GORDON: I think the discussion begins on page 543 and it kind of intertwines a little bit, but --
THE EXAMINER: Can I suggest, Mr. Reed, that you allow Mr. Gordon to ask his questions and answer them and then before we leave this document, you can make any point you wish to make about it, unless you think it is essential for you to lay down your marker before you answer questions about it.
A. I would prefer to do that, if that is okay.
THE EXAMINER: Fine. Do it that way.
A. So when I was reading this documentation yesterday and going through e-mails, it's clear to me that some of the data on the clinical side of the paper is wrong, slightly wrong. It doesn't affect the conclusion of the paper and there's still a significant difference. But there is, in fact, one more infection in each group.
Now, this was e-mailed to Mark Albrecht and he did

reply to it and, in fact, it's in your documents; the e-mail correspondence. And he says he will put it into the main paper and, in fact, he then says he has put it in the main paper, but unfortunately it's slightly old data that is in the main paper. It does not affect the conclusion in any way, but nevertheless it is not the latest data they have got in there, and I don't know why that is.
THE EXAMINER: If Mr. Gordon points you to that specific section, then you can identify it for us.
A. I will ...
BY MR. GORDON:
Q. I am sure we will get to those details.
Just broadly speaking, the clinical component of it was a retrospective observation analysis of infection data; is that correct?
A. So I mean, the data is collected prospectively. So it is not that we look back. It is collected live. So it is prospective in that sense, but I would say it is opportunistic, because we had made the change and then we looked to see what happened. The data is prospective.
Q. Was the data being collected -- were the data being collected for purposes of doing this study?

A. No. We collect data routinely and we have a surveillance team, so that is essentially nursing staff, of which I think we had three at that time, whose job it is purely to look at infection rates, if you like.
Q. Okay. So just again, in broadbrush terms. You had and have a body of infection data and what this study did was to look back at a particular time period; is that correct?
A. Well, we collect --
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. We collect the data as we go, if you like, and we have done since probably, I think, 2007/2008.
BY MR. GORDON:
Q. What is the reference on page 533 to --
THE EXAMINER: 543?
BY MR. GORDON:
Q. 543, thank you. For demographic information on relevant risk factors for surgical site infections, SSI, collected for primary hip and knee replacement procedures performed at our hospitals -- hospital during a 2.5-year period starting 1st July, 2008?
MR. ASSAAD: Where are you reading? I am sorry.

THE EXAMINER: At the top of --
MR. GORDON: At the beginning of the text on page --
MR. ASSAAD: Oh, thank you.
THE EXAMINER: Sorry, what was the question arising out of that?
BY MR. GORDON:
Q. What does that refer to?
A. Well, that's essentially the data that we collect on patients as they come in and have a joint replacement.
Q. Did you just start collecting that data on 1st July, 2008?
A. I think that's probably about right, yes. That's when we went to full-time surveillance. We didn't have a surveillance team. We had part-time surveillance. So in England, there's the -- the NHS law is that you have to submit the one quarter every year, one operation infection rates. And we moved to full-time surveillance in that time. So we had a complete handle on infection rates from that point.
Q. And at the end of that 2.5-year period, did you stop collecting data?
A. No. We still collect data.
Q. The 2.5-year period is the -- would be the time period of the McGovern paper; right? That's -- it's just

a finding that what -- the book-ends of the study?
A. Yes.
Q. Okay.
So when you -- at the start date of 1st July, 2008, patients were being warmed with the Bair Hugger; is that correct?
A. Yes.
Q. And at some point, you transitioned over from warming patients with the Bair Hugger to warming them with the Hot Dog; is that correct?
A. Yes.
Q. And at some point, you were fully transitioned and only had -- were only using the Hot Dog?
A. Yes.
Q. Is that correct?
A. Yes.
Q. So there were really three periods in that 2.5 years. The first period being Bair Hugger only; the second period being transition; and the third period being Hot Dog; is that correct?
A. Yes.
Q. What was the period of Hot Dog only use?
A. So that's in the paper. It's from -- it was something like June till -- until the end of December.

Q. Of ...?
THE EXAMINER: Where is this?
A. So this is page 546. And it's the chart which has been written on.
THE EXAMINER: Oh, I see.
BY MR. GORDON:
Q. So June to December 2010?
A. Yes, I think it's June.
MS. ZIMMERMAN: What page was this?
MR. HOLL-ALLEN: 546. This is the table ...
BY MR. GORDON:
Q. Would that be seven months?
A. It feels about right. Six or seven months.
MR. ASSAAD: There's markings on this page. Did you mark ...
THE EXAMINER: I am a bit confused to where the proper lines are, in the light of all these ...
So you used the Bair Hugger from July 2008 to March -- February/March 2010?
A. No. So the -- what's the best way to explain this chart? So if you can try and ignore the scribbles.
THE EXAMINER: Yes, I am trying to.
MR. HOLL-ALLEN: Sir, I am sorry to interrupt. In the plaintiffs' file, there is a clean copy of the same

document.
THE EXAMINER: Thank you. I don't have the plaintiffs' file.
MR. ASSAAD: And I would prefer to use that, because it seems that this document was used during the Albrecht deposition that was taken in October(?) 2016 and I had to have -- these markings could influence the witness's testimony today. So I would rather have a clean copy.
THE EXAMINER: That is another reason. The principal reason is that it's virtually impossible to understand, with all these markings on it.
MR. HOLL-ALLEN: Would you like to use my copy, sir?
THE EXAMINER: No, it is more important that you have it than I do.
BY MR. GORDON:
Q. Well, let's skip that chart. If you go back to page 543 --
MR. ASSAAD: Are you moving on to the ...
MR. GORDON: No, that was the ...
THE EXAMINER: Which one of these is ...?
A. I think --
BY MR. GORDON:
Q. Under "Joint infection data", there is a reference to: a transition of warming -- forced air warming to

THE EXAMINER: Okay.
A. I mean, there is an enormous amount of operations that fall into those groups. You are probably right, but I don't -- I think a coder wouldn't rely on that to say whether it was trauma or not.
BY MR. GORDON:
Q. When you initially saw a printout of data for use in the McGovern study, did you limit it to non-trauma, hip and knee surgeries?
MR. ASSAAD: Objection, misstates the prior testimony. Lack of foundation. He never stated he saw a printout.
THE EXAMINER: You can answer.
A. So normally, the patients you get on here are elective. So there will be some that come on, that are not elective, and then they will be removed by the surveillance team and put -- not actually removed, but put into a different category of joint replacement.
BY MR. GORDON:
Q. When you compiled the data for the McGovern study, did you in any way try to separate the trauma and the non-trauma patients?
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. I mean, we definitely attempted to do that, because this

database is meant to be just planned cases, just elective cases.
BY MR. GORDON:
Q. Okay. And by --
A. But we do know that other ones get in through coding and then they will be taken out in the sort of data cleaning process.
Q. By this database, you mean the 788 through 1050 -- 1081?
A. So you know, before we would publish, if you like, on infection rates, then we would go through it, we would check every case is as -- you know, every case, whether the infection is trauma or not. You might by chance end up pulling one out, you might not. I am not aware whether we did with this study.
Q. Okay. The data here, on 788 through 1081, as Mr. Dyer pointed out, began on 1st October, 2007. What was your reasoning for commencing the Bair Hugger only period on 1st July, 2008?
A. So my recollection is that we got a full-time surveillance team at that point. So as I said, previously in the U.K. you only have to do a quarter. Actually, you can choose which operation you do. So you might not have full-time surveillance prior to that.
THE EXAMINER: So one operation, one quartile, per annum?

A. Correct. That's the national standard. But we have moved to doing every operation full-time; and that's why we have got that reliable data. So there would be big gaps in the period. If you looked at 2006, you might only have a quarter of the year populated, which would be very unreliable data.
THE EXAMINER: Yes.
BY MR. GORDON:
Q. So I really want to drill down on the timing; and that is critical. I am going to ask you to take a look at volume 2, pages 487 through 490.
A. Okay.
Q. Have you seen this before?
A. I saw it yesterday.
Q. Is that the first time you saw it?
A. I'm not sure.
MR. ASSAAD: I am going to object for lack of foundation for any questions being asked, if he hasn't established foundation. He has written this document -- the authorship of this document --
THE EXAMINER: You have made your objection. Keep objections short.
MR. ASSAAD: Well, I need to put all the objections for the U.S. court.

THE EXAMINER: I know.
MR. GORDON: They are all preserved.
THE EXAMINER: I am familiar with how U.S. attorneys --
MR. ASSAAD: They are --
MR. GORDON: The only objection is: waives form or foundation.
MR. ASSAAD: I am only doing it for trial --
BY MR. GORDON:
Q. Do you know who Julie Gillson is?
A. Yes. Julie Gillson was one of our matrons.
Q. What is a matron?
A. So it is a senior nurse, essentially.
Q. Was she one of the SSI surveillance nurses?
A. No. So Julie is a matron, so the senior nurse within surgery, if you like. Gail Lowdon leads the surgical site infection surveillance team.
Q. And if you look at the front page of this document. At page 71, the very last paragraph, it says during --
THE EXAMINER: Where are you?
BY MR. GORDON:
Q. Page 71. Oh, I am sorry.
THE EXAMINER: 487.
MR. GORDON: 487, thank you. Page 487, the last full paragraph on the page:

THE EXAMINER: They were at that time?
A. Yes. So this -- briefly, this is a paper where we asked other hospitals around the country that had changed similarly to us, to get in touch; and then we analyzed their data remotely to see what the complications had been.
BY MR. ASSAAD:
Q. And xarelto does not increase increased particles or bacteria to the surgical site; correct?
A. Correct.
Q. I would like you to refer to page 1556.
(Off the record remarks.)
Q. Now, Mr. Reed, you would agree with me that if someone has a peri-prosthetic joint infection, they would have to be returned to the operating room; correct?
A. Almost certainly. Very rarely not.
Q. Okay. So if you look at this document, you have wound complications using xarelto, as compared to a low molecular weight heparin. And then you have, two below it, return to surgery from infection. Do you see that?
A. Yes.
Q. And do you agree with me that if we are looking at PJIs, we should be looking at the differences between xarelto and the low molecular weight heparin for returning to

surgery for infection; correct?
A. Yes, correct. I just have the caveat that I don't know what timescale this looks at. But it is probably within 30 days, which would be a reasonable thing to look at.
(Off the record remarks.)
Q. So would you agree with me that the change from the low molecular weight heparin in the McGovern study to xarelto in the return had no effect; it was not a confounding factor with respect to the infection rates?
A. So based on this study of 12,000 patients, I would say there was no effect on return to surgery from infection.
Q. So would you agree with me that based on this study, that you are an author of, that looking at the date of the McGovern paper, that now we can exclude xarelto as a confounding factor for infection rates?
A. I think that's what this paper says.
THE EXAMINER: Because you nevertheless thought it appropriate to refer to the change in the McGovern paper.
A. Yes, because in our paper, there wasn't a significant difference in infection rates. But there was a signal; that was -- so that's why I put it in. It is safer to be upfront and fair about it.

BY MR. ASSAAD:
Q. And we had a discussion today about the unidirectional airflow in the operating rooms; correct?
A. Yes.
Q. And you believe that it prevents -- using unidirectional flow prevents peri-prosthetic joint infections?
A. Yes.
Q. Because it reduces the particles in the operating room; correct?
A. Yes.
Q. There is an argument that has been made with respect to critiquing your McGovern article, that laminar flow actually increases peri-prosthetic joint infections. Have you heard that argument before, regarding your article?
A. Yes.
Q. And you are of the opinion that, in fact, that needs to be looked at, because you think the forced air warming has an effect on the laminar unidirectional airflow; correct?
A. Yes. I think it may have an effect on that data.
Q. And actually you have written about that in the book chapter published in 2016; correct?
A. Yes, very likely.

Q. We have also discussed keeping patients warm during the preoperative and perioperative period; correct?
A. Yes.
Q. And you believe one or the other is fine; correct? Or I could have misunderstood you.
A. Well, it's not -- you haven't misunderstood me, but I think in terms of where the evidence is, I think that's possibly where the evidence is; one or the other is fine. But I would say the best practice now is to do both. And in fact, the NICE guidance draft, which has just come out, will be to do pre-warming and warming during surgery.
Q. But you agree that there's no evidence, scientific evidence, that indicates that keeping a patient warm during surgery and before surgery reduces peri-prosthetic joint infections?
A. So do -- okay. So there's definitely evidence that in colorectal surgery, that keeping people warm reduces their infection rate. And there is evidence from David Leaper's study, who you are going to meet, that pre-warming patients reduces infection rates in their clean surgery. But that is not during the operation. That is before.
I would say there isn't any evidence that doing

involved in this pilot study?
A. A little earlier than this; but I don't think they have signed contracts. I'm not aware they have signed contracts. So normally these things actually evolve over several months.
So were they discussing it in July? I think there probably was an expression of interest and an understanding that 3M may fund it, I believe.
Q. Do you know Dr. Mark Harper?
A. Yes.
Q. How do you know Dr. Mark Harper?
A. Well, we sit on the NICE guidance committee together. I run an infection prevention meeting in the North, which he spoke at about a month ago. So I have met him a few -- well, I would say three times.
Q. Do you know that he is on the 3M advisory panel, scientific advisory panel?
A. No, I didn't know that.
Q. Do you know he got paid by 3M?
MR. GORDON: Object to the form of the question.
A. No.
THE EXAMINER: What for?
BY MR. ASSAAD:
Q. For his consulting.

A. No. He may have been the link between 3M and the study, I suppose. He probably was.
Q. I take it the null hypothesis in this study is that there is no difference between forced air warming and resistive fabric warming; correct?
A. Yes.
Q. What is the hypothesis?
A. So we are just trying to tell if there is a difference between the two. And we will decide on numbers, based on the first 1,000 patients that we get in; it will give us a feel for the infection rates and then we will be aiming to show a difference or not between the two.
Q. But what is the working hypothesis, though? There has to be a working hypothesis. Is one better than the other?
A. I am not sure how the stats are structured, to be honest; whether it is an equivalent study or a superiority study.
Q. I think it is a superiority study. So it has to ...
A. Well, I imagine suggesting then that there is a difference, that forced air has a higher infection rate. But I can't remember the detail of that, I am afraid. Unfortunately it's not my study.
Q. What is your involvement in the study going to be?

A. So I have been involved in the design, if you like, of it; and I will be a recruiting center for it. Our trust will recruit patients, I think. That depends a little bit on whether my colleagues are willing to do it. But I mean, this is a study that I have been wanting to do for some time.
Q. Since you published the McGovern study; correct?
A. Since before that. 2009 is when I asked Scott Augustine to fund it. We didn't ask 3M at that point.
Q. And how much is the study going to cost, approximately, this patient study? Is there an estimate?
A. I think -- I have got the figure on my CV. So this is a pilot study, so it is not the whole study. But I think the -- I think 3M and the infection -- Healthcare Infection Society are putting in, was it 117,000 I saw on my CV?
Q. Yes. And are you getting compensated for your time involved in this study?
A. No.
Q. Do you have a contact at 3M that you are dealing with, regarding this study?
A. Regarding this study, no. I have got no involvement with 3M personally, with this study. I do have involvement with a different branch of 3M over my other

randomized trial that I am doing.
Q. Were you aware that other experts such as -- such as Dr. Sessler has also advised 3M over the years back?
MR. GORDON: Object to the form of the question.
BY MR. ASSAAD:
Q. If you go to page ...
Sorry.
(Off the record remarks.)
Q. Page Reed 172, 15 of 22 of the pilot. And this is the pilot study with your name on it; is that correct?
A. Yes.
Q. Okay.
If you look at the fourth line down, under "Warming method and temperature monitoring" under 8. It says:
"Both forced air warming and resistive fabric warming are established and licensed for use in the U.K. and are equally effective at preventing inadvertent perioperative hypothermia."
Did I read that correctly?
A. I can't see where you are reading it, but what you said --
Q. Under "Warming method" --
THE EXAMINER: Right down at the bottom of the page.
BY MR. ASSAAD:

Q. The third line up from the bottom.
A. Yes. Yes.
"... are established and licensed for use in the U.K. and are equally effective at preventing inadvertent perioperative hypothermia."
Yes. I think that is a reasonable statement.
THE EXAMINER: So the primary function, they are equivalent.
A. In terms of warming, yes, I think that is a fair summary. I think even that is debated, but yes.
BY MR. ASSAAD:
Q. Mr. Reed, you stand by your studies; correct?
A. Yes.
Q. And even though Mr. Albrecht and Dr. Augustine were funding the studies involved, they did not influence the data or the results that you have concluded; correct?
A. Yes. So just to be clear, there was no funding for any of these studies apart from the very first one, which was the one actually that didn't show any difference. But yes, I do stand by them, yes.
MR. ASSAAD: All right. At this time, under the Federal Rules of Evidence, I am going to offer him as an expert and the stuff he has testified in, with respect to orthopaedic surgery, peri-prosthetic joint infections and the causation of peri-prosthetic joint infections.

And after that, I have no further questions.
THE EXAMINER: I am sorry, you are going to have to say that again.
MR. ASSAAD: I am offering him as an expert in the testimony he has given to his studies, with respect to orthopaedic surgery, general causation on peri-prosthetic joint infections and general peri-prosthetic joint infections under the Federal Rules of Evidence.
THE EXAMINER: I don't know what you mean by "offering him as an expert". However, he is not here specifically under the terms of the U.K. order to give expert evidence, on the basis that both parties have their own experts in the United States.
Now, if you want to try and change this into something different in the U.S.A., that is a matter between the parties and the judge but I want to make it crystal clear that he has not been giving evidence today in this room as an expert. Okay?
Now, Mr. Gordon, it seems to me on the timescale, you have about 20 seconds left for re-examination.
MR. GORDON: I thought it was more like 40.
FURTHER EXAMINATION BY MR. GORDON:
Q. Mr. Reed, when counsel asked you about the McGovern studies showing an odds ratio of 3.8, and he asked you

to agree with him, or whatever the exact words were, I can't remember. But essentially that using forced air warming was 3.8, and it increased the rate of infection 3.8 times over the other warming modality and you said "based on that paper".
Two questions.
First of all, why in the paper did you say:
"This study does not establish a causal basis for this association."
MR. ASSAAD: Objection to form.
THE EXAMINER: You may answer.
A. Because it doesn't. It doesn't establish causation, our paper. The -- yes, okay.
BY MR. GORDON:
Q. So what did you -- when you said "based on that paper", I mean, what was it that you were saying?
A. So as I said right at the start, right at the start of the proceedings, I said I wanted to mention something about that paper.
And -- in that we -- there was some very up to date data which I thought was in it. It does not actually change the material effect of the paper. You know, the conclusions are still the same.
But that final data that we got in, for some reason,

did not get into the final paper. It might -- it did change the odds ratios very slightly. That's the reason that I mention it.
So it might not be 3.9. It was probably 3.8 or something like that. But I think it is somewhere in here. We could look it up.
Q. But regardless of whether it's 3.8 or 3.9 or ...
What does it mean that there is -- that the study does not establish a causal basis?
MR. ASSAAD: Objection. I think his time is up.
THE EXAMINER: I think I will allow you to answer this question and then that's it.
A. So what we have shown is association and not causation. We made that pretty clear in the paper.
THE EXAMINER: Okay.
MR. GORDON: Thank you.
THE EXAMINER: Thank you very much.
MR. ASSAAD: Thank you.
THE EXAMINER: That concludes your examination, Mr. Reed. Thank you very much indeed.
THE VIDEOGRAPHER: This is the end of the deposition of Michael Reed. We are going off the record at 5:53.
(5:53 p.m.)
(Whereupon the deposition concluded.)